



## Uniform Formulary Medical Necessity Criteria for Contraceptives

**Drug Class** - Contraceptives. This drug class includes oral, transdermal (skin patch), vaginal ring, and injectable contraceptives.

**Background** - After evaluating the relative clinical and cost effectiveness of contraceptives, the DoD P&T Committee recommended that the following medications be designated as non-formulary. This recommendation has been approved by the Director, TMA.

Effective date 4 January 2012

Patients currently using a nonformulary contraceptive may wish to ask their doctor to consider a formulary alternative.

### Uniform Formulary Status, Cost Shares, and Therapeutic Alternatives for Contraceptives<sup>1,2</sup>

Uniform Formulary Status	Medication	Military Treatment Facilities (MTFs) (up to a 90 day supply)	TMOP (up to a 90 day supply)	Retail Network (up to a 30-day supply)
Non-Formulary (Tier 3)	Eurostep Fe, Loestrin 24 Fe; Ovcon-35/Femcon FE, Ovcon-50, Lybrel, Beyaz, LoLoestrin Fe, Sayfrol	Not available <sup>2</sup>	Non-Formulary cost share applies	Non-Formulary cost share applies
	Seasonale & generic equivalents (EXCEPT Jolessa); Seasonique, LoSeasonique; these products are packaged as a 3-month supply <sup>3</sup> , Natazia	Not available <sup>2</sup>	Non-Formulary cost share applies	Non-Formulary cost share applies
Formulary: Brand Name (Tier 2)	Depo-Provera 104, Ortho-Evra (patches), Ortho Tri-Cyclen Lo, Nuvaring (vaginal ring), Plan B, Yasmin, Yaz	\$0	Formulary (Brand) cost share applies	Formulary (Brand) cost share applies
Formulary: Generic (Tier 1)	Numerous oral contraceptives, Jolessa (3 month packaging), depot medroxyprogesterone acetate injection (150 mcg/mL)	\$0	Generic cost share applies	Generic cost share applies

1. Active duty cost share always \$0 in all points of service for all three tiers; TRICARE does not cover non-formulary medications for active duty service members unless they are determined to be medically necessary.
2. MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.
3. A 3-month supply of contraceptives may be obtained from retail pharmacies by paying 3 cost shares.

## Medical Necessity Criteria

**Estrostep Fe** - The non-formulary cost share for Estrostep Fe (ethinyl estradiol 20/30/35 mcg; norethindrone 1 mg) may be reduced to the formulary cost share if the patient meets the following criterion:

1. The patient continues to experience troublesome adverse effects (e.g., breakthrough bleeding or spotting) after having tried at least two different formulary oral contraceptives taken on a consistent basis for at least three cycles each; and, in the opinion of the provider, the timing of the adverse effects supports use of a triphasic product that varies estrogen on an increasing basis during the cycle.

**Loestrin 24 Fe, LoLoestrin Fe** - The non-formulary cost share for Loestrin 24 Fe (ethinyl estradiol 20 mcg; norethindrone 1 mg; 24-day regimen) and LoLoestrin Fe (ethinyl estradiol 10 mcg; norethindrone 1 mg; 24-day regimen) may be reduced to the formulary cost share if the patient meets the following criterion. Formulary alternatives include Loestrin Fe 1/20 and Loestrin 1/20, which include the same active ingredients as Loestrin 24 Fe; Alesse, Levlite, or equivalents; and Yaz, which is also packaged as a 24-day regimen.

1. Use of ALL other formulary oral contraceptives containing 20 mcg of estrogen and a progestogen other than 1 mg norethindrone is precluded due to previous lack of tolerance, contraindication, or other clinical consideration AND the patient cannot be treated with generic equivalents to Loestrin Fe 1/20 or Loestrin 1/20 (which contain the same active ingredients packaged as a conventional 21-day on, 7-day off regimen) due to hypersensitivity to an inactive ingredient (e.g., dye or excipient).

**Ovcon 35/Femcon FE** - The non-formulary cost share for Ovcon 35 (ethinyl estradiol 35 mcg/ 0.4 mg norethindrone) may be reduced to the formulary cost share if the patient meets any of the following criteria. Please note that formulary products very similar to Ovcon 35/Femcon FE are available, including products containing ethinyl estradiol 35 mcg/0.5 mg norethindrone (e.g., Brevicon, Necon 1/35, Nortrel 0.5/35).

1. Use of ALL formulary oral contraceptives containing 35 mcg of estrogen is contraindicated (e.g., due to hypersensitivity), and treatment with Ovcon 35/Femcon FE is not contraindicated.
2. The patient has previously tried and could not tolerate ALL formulary oral contraceptives containing 35 mcg of estrogen AND the patient cannot reasonably be treated with a lower estrogen product in an attempt to decrease the likelihood of adverse effects.
3. The patient requires a product containing norethindrone due to previous lack of tolerance, contraindication, or other clinical consideration precluding use of products containing norgestimate, ethynodiol diacetate, or levonorgestrel; AND has a contraindication or a clinical consideration precluding treatment with ethinyl estradiol 35/0.5 mg norethindrone, which is on the formulary.

**Ovcon 50** - The non-formulary cost share for Ovcon 50 (ethinyl estradiol 50 mcg/1 mg norethindrone) may be reduced to the formulary cost share if the patient meets any of the following criteria. Please note that formulary products similar to Ovcon 50 are available, including products containing mestranol 50 mcg/1 mg norethindrone (e.g., Norinyl 1+50, Necon 1/50).

1. Use of ALL formulary oral contraceptives containing 50 mcg of estrogen is contraindicated (e.g., due to hypersensitivity), and treatment with Ovcon 50 is not contraindicated.
2. The patient has previously tried and could not tolerate ALL formulary oral contraceptives containing 50 mcg of estrogen AND the patient cannot reasonably be treated with a lower estrogen product in an attempt to decrease the likelihood of adverse effects.
3. The patient requires a product containing norethindrone due to previous lack of tolerance, contraindication, or other clinical consideration precluding use of products containing ethynodiol diacetate or norgestrel; AND has a contraindication or a clinical consideration precluding treatment with mestranol 50 mcg/1mg norethindrone, which is on the formulary.

**Seasonale & its generic equivalents (e.g., Quasense)** – These products are packaged in 3 month supplies, requiring 3 cost shares with each dispensing. The non-formulary cost share may be reduced to the formulary cost share if the patient meets the following criterion.

Please note that a 90-day supply of formulary products (e.g., Levora 0.15/30, Portia) containing the same amounts of the same estrogen and progestogen components (ethinyl estradiol 30 mcg; levonorgestrel 0.15 mg) are available in conventional 28-day packages (each containing 21 active tablets) at a total cost share (three generic cost shares) in the retail network and at mail order. A total of 4 packages (84 active tablets) would be required for a 3-month supply following a 84-day on, 7-day off regimen.

1. The patient has previously used conventionally packaged oral contraceptives on an extended cycle basis; AND has had difficulties complying with the extended cycle regimen that have increased the risk of pregnancy or necessitated the use of back-up contraception on one or more occasions, despite adequate instructions for use AND in the provider's opinion, these difficulties are likely to be remedied by special packaging.

**Seasonique, LoSeasonique** - These products are packaged in 3 month supplies, requiring 3 cost shares with each dispensing. The non-formulary cost share may be reduced to the formulary cost share if the patient meets the following criterion. Seasonique is packaged as a 3-month supply (84 days of combination tablets (ethinyl estradiol 30 mcg; levonorgestrel 0.15 mg) plus 7 days of low-dose estrogen tablets (10 mcg ethinyl estradiol)).

1. The patient has previously used conventionally packaged oral contraceptives on an extended cycle basis AND has had difficulties complying with the extended cycle regimen that have increased the risk of pregnancy or necessitated the use of back-up contraception on one or more occasions, despite adequate instructions for use AND, in the provider's opinion, these difficulties are likely to be remedied by special packaging.

**Lybrel** - The non-formulary cost share for Lybrel may be reduced to the formulary cost share if the patient meets the following criterion. Lybrel is packaged as 28 active tablets with no placebo tablets and is intended to be taken on a continuous basis.

1. The patient has previously used conventionally packaged oral contraceptives on an extended cycle basis AND has had difficulties complying with the extended cycle regimen that have increased the risk of pregnancy or necessitated the use of back-up contraception on one or more occasions, despite adequate instructions for use AND, in the provider's opinion, these difficulties are likely to be remedied by special packaging.

**Natazia** - The non-formulary cost share for Natazia may be reduced to the formulary cost share if the patient meets the following criterion. Natazia is packaged as 28 active tablets with no placebo tablets and is intended to be taken on a continuous basis.

1. Use of ALL formulary oral contraceptives is contraindicated (e.g., due to hypersensitivity), and treatment with Natazia is not contraindicated.
2. No alternative formulary agent available (if other oral contraceptive agents do not provide adequate bleeding and cycle control)

**Beyaz** - The non-formulary cost share for Beyaz may be reduced to the formulary cost share if the patient meets the following criterion. Beyaz contains the same contraceptive ingredients in the same strength as Yaz and its generic equivalents, but with the addition of 0.451mg of levomefolate.

1. Use of ALL formulary oral contraceptives is contraindicated (e.g., due to hypersensitivity), and treatment with Beyaz is not contraindicated.

**Safyral** - The non-formulary cost share for Sayfral may be reduced to the formulary cost share if the patient meets the following criterion. Safyral contains the same contraceptive ingredients in the same strength as Yasmin and its generic equivalents.

1. Use of ALL formulary oral contraceptives is contraindicated (e.g., due to hypersensitivity), and treatment with Safyral is not contraindicated.

Medical necessity criteria recommended by the DoD Pharmacy & Therapeutics Committee at the Aug 2011 meeting and approved by the Director, TMA on 28 October 2011. For more information, please see DoD P&T Committee minutes.

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# TRICARE Pharmacy Program Medical Necessity Form for Ovcon 35 and Femcon Fe



5548

This form applies to the TRICARE Pharmacy Program (TPharm). The medical necessity criteria outlined on this form also apply at Military Treatment Facilities (MTFs). The form must be completed and signed by the prescriber.

- Contraceptives on the DoD Uniform Formulary include the majority of oral, transdermal, vaginal ring, and injectable contraceptives available in the U.S. **Ovcon 35 (and generics: Balziva, Briellyn, and Zenchent) and Femcon Fe are non-formulary, but available to most beneficiaries at the non-formulary cost share.** Formulary alternatives with 35 mcg of estrogen are listed on the form below.
- You do **NOT** need to complete this form in order for non-active duty beneficiaries (spouses, dependents, and retirees) to obtain Ovcon 35 or Femcon Fe at the non-formulary cost share. The purpose of this form is to provide information that will be used to determine if the use of Ovcon 35 or Femcon Fe instead of a formulary medication is medically necessary. If Ovcon 35 or Femcon Fe is determined to be medically necessary, non-active duty beneficiaries may obtain it at the formulary cost share.
- Active duty service members may not fill prescriptions for Ovcon 35 or Femcon Fe unless it is determined to be medically necessary. There is no cost share for active duty service members at any DoD pharmacy point of service.

MAIL ORDER and RETAIL	<ul style="list-style-type: none"> <li>The provider may <b>call: 1-866-684-4488</b> or the completed form may be <b>faxed to: 1-866-684-4477</b></li> <li>The patient may attach the completed form to the prescription and <b>mail it to: Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954</b> or <b>email the form only to: TpharmPA@express-scripts.com</b></li> </ul>	MTF	<ul style="list-style-type: none"> <li>Non-formulary medications are available at MTFs only if <b>both</b> of the following are met:                             <ul style="list-style-type: none"> <li>The prescription is written by a military provider or, at the discretion of the MTF, a civilian provider to whom the patient was referred by the MTF.</li> <li>The non-formulary medication is determined to be medically necessary.</li> </ul> </li> <li>Please contact your local MTF for more information. There are no cost shares at MTFs.</li> </ul>

## Step 1 Please complete patient and physician information (Please print)

Patient Name: _____	Physician Name: _____
Address: _____	Address: _____
Sponsor ID #: _____	Phone #: _____
Date of Birth: _____	Secure Fax #: _____

## Step 2 Please explain why the patient cannot be treated with the formulary medications:

Please indicate which of the reasons below (1-3) applies to each of the formulary medications listed in the table. You **MUST** circle a reason **AND** supply a written clinical explanation specific for **EACH** formulary medication. Please note that several of the formulary medications are very similar to Ovcon 35 and Femcon Fe (these two agents contain 35 mcg EE; 0.4 mg norethindrone).

Formulary Medication	Reason	Clinical Explanation
EE 35 mcg; 0.5 mg norethindrone (Modicon equivalent)	1 2 3	
EE 35 mcg; 1.0 mg norethindrone (Ortho-Novum 1/35 equivalent)	1 2 3	
EE 35 mcg; 0.25 mg norgestimate (Ortho-Cyclen equivalent)	1 2 3	
EE 35 mcg; 1.0 mg ethynodiol diacetate (Demulen 1/35 equivalent)	1 2 3	
EE 35 mcg; 0.5/0.75/1 mg norethindrone (Ortho-Novum 7/7/7 equivalent)	1 2 3	
EE 35 mcg; 0.5/1/0.5 mg norethindrone (Tri-Norinyl equivalent)	1 2 3	
EE 35 mcg; 0.18/0.215/0.25 mg norgestimate (Ortho Tri-Cyclen equivalent)	1 2 3	

EE = ethinyl estradiol; Note: The formulary medications listed above only include formulary oral contraceptives with 35 mcg ethinyl estradiol. However, the majority of oral, transdermal, vaginal ring, and injectable contraceptives are available on the Uniform Formulary.

### Acceptable clinical reasons for not using a formulary medication are:

- Use of the formulary alternative is contraindicated (e.g., due to hypersensitivity).
- The patient has been unable to tolerate the formulary alternative and cannot reasonably be treated with a lower estrogen product in an attempt to decrease the likelihood of adverse effects.
- Use of the formulary alternative is precluded due to its progestogen component (e.g., norgestimate, ethynodiol diacetate, or levonorgestrel) due to inability to tolerate, a contraindication, or another clinical consideration.

## Step 3 I certify the above is correct and accurate to the best of my knowledge. Please sign and date:

3

Prescriber Signature

Date

Latest revision: September 28, 2011